REMARKS

As a preliminary matter, the Examiner's comments relating to the Information Disclosure Statement (IDS) are noted. Apparently a copy of the Szejtli article listed on Applicant's most recent IDS was inadvertently omitted. A supplemental IDS is included with this response, with which a copy of the Szejtli article has been re-submitted.

Claims 1 through 3 are in the application. All three claims stand rejected as being anticipated by Chiesi, US 5,773,029, the Examiner having commented, in pertinent part, as follows:

> The Chiesi et al. patent discloses multicomponent inclusion complexes wherein a multicomponent inclusion complex comprises an acidic drug, a base and a cyclodextrin, wherein a complex is obtained by simultaneous salt formation and complexation. See column 2, lines 54-61 for examples of cyclodextrin derivatives that can be used in the preparation of the inclusion complexes which include alfa and gamma CD, hydroxyporpyl-βCD (HPBCD), dimethyl-βCD (DIMEB), random methylated-β-cyclodextrin (RAMED) and other cyclodextrin derivatives. In the next 2 paragraphs in this column Chiesi et al. discloses that the basic component of the complexes according to the invention can be of both inorganic and organic nature, which specific examples include alkali or alkaline earth hydroxides, secondary or tertiary amines, such as diethanolamine, triethanolamine, diethylamine, methylamine, trimethamine (TRS) and the like. In the first two paragraphs in column 3 Chiesi et al. describes the type of acidic drugs used in patient which is set forth to mean any drug having at least an acidic function such as a carboxy, sulfonic, sulfonylamino, sulfonylureic, phenol group and the like. Examples of classes of the acidic drugs disclosed by Chiesi et al. comprises oxicams, hypoglycemic sulfonylureas, benzothiadiazine diuretics, barbturic acids, arylacetic and arylpropionic anti-inflammatory acids. See column 6, lines 57-62 wherein Chiesi et al. describes Tables 1 and 4 as setting forth equilibrium solubility of some drugs used for the preparation of the complexes of the invention therein, wherein respective sodium salts and the physical mixture with βCD is used to determine the maximum solubility conditions at equilibrium. Also see Tables 2 and 4 wherein the instant solubility is determine for multicomponents Glibenclamide/βCD/NaOH, Glibenclamide/βCD/Diethanolamine, Piroxican/RAMEB/NaOH, and Piroxican/HPβCD/NaOH. The information set forth in Tables 1, 2 and 4 of the Chiesi et al. patent allows for a comparison of the solubility properties of a series of salt, including salt of medicinal compounds as set forth in Claim 2 and salts for use to make a composition of matter comprising an inclusion complex of a salt in a cyclodextrin as set forth in Claim 3. The method described in the Chiesi et al. patent for preparing multicomponent inclusion complexes anticipate the method of locating one or more salts of a compound and a method of determining a useful salt from within a series of salts as instantly claimed.

It is noted that the above wording was employed in rejecting the application under both 35 USC §102(a) and 35 USC §102(e).

So far as the rejection under §102(e) is concerned, it is noted that Applicant does not, on the merits, agree with the rejection for the same reasons as those given below in responding to the rejection under §102(a). Regardless of the merits of the §102(e) rejection and the reasoning presented by the Examiner, Chiesi is not a reference under §102(e) and the rejection should be withdrawn for that reason. The Chiesi §102(e) date is given on the title page of US 5,773,029 as October 22, 1996. That date, so far as the undersigned is aware, is not affected by the AIPA. The instant application was filed claiming priority from Applicant's US Provisional Application No. 60/016,866 filed May 7 1996, the provisional date therefore being prior to the Chiesi §102(e) date. See Applicant's declaration which was submitted together with the original filing papers for this application and in which priority to the aforementioned provisional application was claimed. Also, see Applicant's Preliminary Amendment that was also filed as part of the original filing papers for this application, and that entered a sentence claiming domestic priority. Applicant thus invokes her right of domestic priority under 35 USC §119(e). Withdrawal of the §102(e) rejection is accordingly respectfully requested.

The rejection over Chiesi under §102(a) is traversed on the basis that it does not meet the legal requirements to constitute an anticipation. The standard for anticipation is one of strict identity, meaning that for prior art to anticipate, it must contain all essential elements of the claimed invention. See Hybritech Inc. v. Monoclonal Antibodies, Inc.231 USPQ 81 (Fed Cir 1986). See In re Donohue, 226 USPQ 619 (Fed Cir 1985) where it was stated:

> an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.

It is hornbook law that a reference (in this case, Chiesi, which is a printed publication) must adequately describe the invention. See Chisum On Patents, Donald S. Chisum, Release No. 85, October, 2002, Matthew Bender, Volume 1 Chapter 3.04[1] at page 3-40:

> To constitute an anticipation, a printed publication must describe the invention. The description must be adequate to a person with ordinary skill in the art to which the invention pertains. By the weight of authority, the description must enable such a person not only to comprehend the invention but also to make it. The listing of a chemical compound by name or formula as a speculative or theoretical possibility will not constitute an anticipation though it is evidence of obviousness.

A reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. In re Paulsen, 31 USPQ2d, 1671 (Fed Cir 1994) at 1673.

Chiesi not only does not disclose the elements of Applicant's invention, Chiesi is unrelated. Chiesi teaches the formation of multicomponent inclusion complexes of acidic drugs with cyclodextrins in the presence of bases in set molar ratios, and teaches that the presence of base gives rise to the formation of complexes that are easily soluble with high concentrations of both guest and host molecules (column 3, lines 33-38). Chiesi thus teaches, in essence, that the aqueous dissolution of an inclusion complex of an acidic drug with a cyclodextrin can be facilitated by adding a base. Chiesi presents examples that evaluate the solubility of acidic drugs with CDs based on a number of variables such as pH, different bases, and different molar ratios of cyclodextrin and base.

Chiesi does not teach Applicant's invention, however. Chiesi teaches that the solubility of a given acidic drug/cyclodextrin complex can be enhanced by adding base. For example, Chiesi does not teach locating a salt having a solubility greater than or equal to a target solubility, as required by Applicant's claim 1. Chiesi does not teach comparison/selection steps as required by claims 2 and 3. Chiesi in fact neither teaches, discloses, or even remotely suggests anything relating to any process by which a particular salt having a desired solubility equal to or greater than a target solubility can be located.

Further, Chiesi does not provide any disclosure that could constitute an anticipation. The Examiner cited Tables 1, 2 and 4 as supporting the §102(a) anticipation rejection, but the data in those tables do not support anticipation (or obviousness, for that matter). There is nothing in Chiesi that teaches or suggesting making solubility comparisons in the manner of Applicant's invention to locate a salt having a solubility in excess of a target solubility

In respect of Table 1, all of the data is directed to a comparison of the solubility of gibenclamide, its sodium salt, and a physical mixture thereof with ß-CD. No other salt is presented in Table 1 and, therefore, no comparison with other salts could be made even if so desired. Also, no two data points were taken under the same conditions?

In respect of Table 2, it is difficult to say exactly what the data in Table 2 might imply in respect of Applicant's claims since conditions (i.e., ratios of the amounts of drug to CD to base, pH, and time) vary where any comparisons between individual data

points for different salts might be made. Most importantly, where any such direct comparisons might be made, the comparative values (i.e., the data points at pH 5.61 and 6.50) are identical. Further, because of the different conditions and the fact that the only feasible comparisons have the same value, it is not possible to judge whether different salts have different solubilities in the same cyclodextrin.

It is further noted that although Tables 1 and 2 both deal with gibenclamide, the tables do not collectively facilitate any comparisons because the data relate to different entities. The data in Table 1 relate to gibenclamide, the sodium salt of gibenclamide, and to gibenclamide/CD physical mixtures. The data in table 2 relate to instant solubilities for gibenclamide/CD/base complexes.

In table 4, the base and the acidic compound are the same (i.e. piroxicam and NaOH). No basis for making a comparison is present.

Thus the Examiner is urged to reconsider the rejection. Chiesi relates to an invention that is different from Applicant;s - - increasing the solubility of a given acidic drug/CD complex rather than locating a salt that meets or exceeds a target solubility in a CD. Chiesi does not describe Applicant's invention and nor, for the reasons given above, otherwise provide a basis for anticipation.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejections.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

Date: MAY 20, 2004

James T. Jones
Attorney for Applicant
Reg. No. 30,561

Pfizer Inc
Patent Department
Eastern Point Road
Groton, CT 06340
(860) 441-4903